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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,899	03/31/2004	John Riley Hawkins	101896-662 (DEP5055USNP)	1803
21125 7590 04/20/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER IZQUIERDO, DAVID A	
			ART UNIT 3738	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/813,899

Applicant(s)

HAWKINS ET AL.

Examiner

David A. Izquierdo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-10 and 12-53 is/are pending in the application.
- 4a) Of the above claim(s) 14-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-10 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 March 2007 has been entered.

Response to Arguments

2. Applicant's arguments filed 02 March 2007 have been fully considered but they are not persuasive. Applicant has argued that the amendments to claim 1 are sufficient to overcome the U.S.C. 102(b) rejection in view of the prior art, Landry et al. ("Landry")(U.S. Patent Application Publication Number 2003/0233145). However, the addition of the limitation "such that a portion of the midline marker embeds in a face of a vertebral body" fails to distinguish the instant application from the prior art. Landry describes a process of insertion comprising placement of the insertion guides (midline marker) adjacent the vertebral bodies wherein a separator is forced between the insertion guides in order to force the insertion guides apart and in doing so forces the insertion guides into the adjacent vertebral bodies (paragraph 0184, Figures 40-44). This action constitutes a midline marker which is embedded in the vertebral body until the insertion guides are removed.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Landry et al. (U.S. Patent Application Publication Number 2003/0233145).

5. Landry et al. discloses a method of implanting an artificial disc comprising:

- a. fixing a position of an insertion guide, which acts as a midline marker. Relative to a face of a vertebral body for instant alignment of artificial disc placement;
- b. Inserting a distraction instrument into the intervertebral space using the midline marker as a guide;
- c. Selecting an artificial disc for implantation; and
- d. Inserting the artificial disc in the intervertebral spacing using the midline marker as a guide (P0021-0026).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robie et al. (U.S. Patent Application Publication Number 2002/0161366) in view of Landry et al. (U.S. Patent Application Publication Number 2003/0233145).

8. Robie et al attaches the template (50) to a vertebral body as a midline marker, where the midline marker (50) is inserted in the guide of figure 4a and impacted until embedded with the vertebral body (P0058). An artificial disc (Hedrocel ALIF) is selected for implantation verified, where the size is verified by the insertion depth of the distractor (P0060), shown in Figure 10 and the implant is prepared for implantation (0061) by stuffing the implant with autologous bone. A window is removed from the annulus, where the window is the width of an artificial implant (P0052) and the nucleus pulposus is removed, as is inherent in the discectomy (P0053). For the purposes of claims 7, the distractors (10) will be trial spacers that are changed until an appropriate size is determined (P0056). The endplates are shaped by a reamer instrument (P0059), reamer instruments having blades, where the shaping instrument is guided by the midline marker (50) (P0059). The template is finally removed (P0063). As per claim 8, the trial spacers (10) are contacted by an insertion tool with a pin end (Figure 3B), where the template (50) (midline marker) is inserted with the pin insertion instrument of Figure 4A where the insertion instrument is removed as per the method figures 5-12.

9. However, Robbie et al. fails to disclose the use of a midline marker as a guide. Landry et al. disclose the use of an insertion guide, which acts as a midline marker, as disclosed above. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the use of a guide to direct a distraction member as taught by Landry et al. with a method of implanting an artificial disc, as per Robbie et al. The motivation to combine being

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that a guide will accurately place the distracter within the disc space, as found in Landry et al. (P0022).

10. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robie et al. in view of Landry et al. in further view of Michelson (U.S. Patent Application Publication Number 2002/0058944) Robie et al in view of Landry et al. is discussed supra. However Robie et al in view of Landry et al. does not disclose radiographical markers. Michelson teaches radiographical (P0069) in the same field of endeavor or the analogous art of surgery for the purpose of radiographical imaging. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of radiographical markers, as taught by Michelson, to aid in radiographical visualization as per Robie, in order to assure the implant is aligned properly and to verify the implant (Michelson P0069).

Allowable Subject Matter

11. Claims 12 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Izquierdo whose telephone number is 571-272-1943. The examiner can normally be reached on Monday through Friday from 8:00 am until 4:30 pm.

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13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Izquierdo



Patent Examiner



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700